MAR 17 2000

K000501

510(k) Summary of Safety and Effectiveness

Somnus Medical Technologies, Inc.™
Model S1 Electrosurgical Generator

Intended Use:

The Somnus™ Model S1 Electrosurgical Generator is intended for use with the Somnus Soft Tissue Coagulating Electrodes for the coagulation of soft tissue. The system is intended for use by qualified medical personnel trained in the use of electrosurgical equipment.

Submitted by:

Somnus Medical Technologies, Inc.
285 N. Wolfe Road
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Contact Person:

Steven J. Ojala, Ph. D.
Vice President of Quality, Clinical
and Regulatory Affairs
Telephone: (408) 617-3434

Date Summary Prepared:

February 10, 2000

Name of the Device:

Proprietary Name:	Somnus™ Model S1 Electrosurgical Generator
Common/Usual Name:	Electrosurgical Generator and Accessories
Classification Name:	Electrosurgical Device (per 21 CFR 878.4400)

K000501

Predicate Devices:

Somnus Model S2 (K 970576) (cleared as Model 615)

Description:

The Somnus™ Model S1 Electrosurgical Generator has controls for maximum temperature, energy delivered and time of energy delivery. The unit has readouts for total energy delivered, impedance, maximum power and temperature for two thermocouples. Connectors on the front panel include connector for active electrode and dispersive electrode. The footpedal is connected on the back panel.

Accessories included with the generator are a line power cable and a pneumatic pedal footpedal.

Statement of Intended Use:

The Somnus Model S1 Electrosurgical Generator is intended for use in the coagulation of soft tissue.

This device is intended for use by qualified medical personnel trained in the use of electrosurgery.

Comparison to Predicate Devices:

The Somnus Model S1 Electrosurgical Generator has been carefully compared to legally marketed devices with respect to intended use and technological characteristics. In addition, performance validation testing has been done to validate the performance of the device. The comparison and validation results presented in this 510(k) notification to the FDA show that the device is substantially equivalent to predicate devices and is safe and effective in its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2000

Stephen J. Ojala, Ph.D.
Vice President of Quality, Clinical
and Regulatory Affairs
Somnus Medical Technologies, Inc.
285 North Wolfe Road
Sunnyvale, California 94086

Re: K000501
Trade Name: Somnus Model S1 Electrosurgical Generator
Regulatory Class: II
Product Code: GEI
Dated: February 9, 2000
Received: February 15, 2000

Dear Dr. Ojala:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K000501

Indications for Use

510(k) Number (if known): Not Yet Assigned

Device Name: SOMNUS™ MODEL S1 ELECTROSURGICAL GENERATOR

Indications For Use: The Somnus Model S1 Electrosurgical Generator, in combination with various Somnus electrodes, is indicated for the coagulation of tissue.

This device is intended for use by qualified medical personnel trained in the use of electrosurgery.

Contraindications for Use: The use of the Somnus Model S1 Electrosurgical Generator is contraindicated when, in the judgment of the physician, electrosurgical procedures would be contrary to the best interests of the patient.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _X_ OR **Over-The-Counter Use** _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000501